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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,635	12/12/2005	David Haines	21534-002CIP NATL	9716

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EXAMINER	
BASQUILL, SEAN M	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
04/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,635	HAINES ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *35-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *13 Nov 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Claims 1-34 in the reply filed on 24 March 2009 is acknowledged.

Claims 35-46 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-34 are presented for examination.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) for applications **10/345,856** and **60/350,298** as follows:

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or

sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit

claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-4, 8-14, 16-20, and 24-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,103,756 (hereinafter "Gorsek"), in view of Narsing Rao and Guey-Shang Wu, *Free Radical Mediated Photoreceptor Damage in Uveitis*, 19 PROG. RETINAL EYE RES. 41 (2000) (hereinafter "Rao), and Gisela Velez and Scott Whitcup, *New Developments in Sustained Release Drug Delivery for the Treatment of Intraocular Disease*, 83 BR. J OPHTHALMOL. 1225 (1999) (hereinafter "Velez").

Gorsek describes an orally administrable composition for the treatment of ocular disease such as macular degeneration comprising a combination of nutrients which neutralize free radicals that may contribute to ocular disorders. (C.1, L.5-9, L.25-28). Specifically, the composition includes the carotenoid zeaxanthin, vitamin C, selenium and other trace minerals, bilberry extract, alpha lipoic acid, n-acetyl-cysteine, quercetin, citrus bioflavanoids, and taurine. (C.2, Table 1). Gorsek indicates that the essential nutrients contained in the composition are shown to have a powerful protective effect on the health of the eye to preserve good vision. (C.1, L.43-45).

Gorsek does not specifically describe the actual treatment of either ocular inflammation or macular degeneration, nor is a topical formulation or administration of the compound described.

Rao indicates that ocular inflammation is in part caused by oxygen metabolites, including oxygen free radicals. (Pg. 41-42). Rao indicates that the administration of free radical scavengers and antioxidants may be beneficial in the treatment of ocular inflammation such as uveitis. (Pg. 62).

Velez indicates that the blood-ocular barrier is a major obstacle in the treatment of intraocular disease with systemic medication, and that the topical administration of medications can successfully treat a number of ocular diseases including inflammation of the ocular surface and posterior segment diseases such as glaucoma. (Pg. 1225).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to have used the composition of Gorsek in the treatment of macular degeneration as well as ocular inflammation as suggested by Rao. One having ordinary skill in

the art would have been motivated to do so because of Rao's suggestion that antioxidants may effectively treat ocular inflammation caused in part by free radical damage, and the fact that Gorsek discloses the usefulness of the composition therein described in protecting against the damage caused by free radicals through their neutralization. Furthermore, it would have been prima facie obvious for one having ordinary skill in the art at the time of the instant invention to have modified the composition of Gorsek for topical ophthalmic administration. One having ordinary skill in the art would have been motivated to do so given the teaching of Velez that topical administration of ocular therapeutics avoids problems associated by the systemic administration of ocular therapeutics.

2. Claims 1-14, and 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek as modified by Rao and Velez as applied to Claims 1-4, 8-14, 16-20, and 24-33 above, and further in view of U.S. Patent Application Publication 2002/0095000 (hereinafter "Troyer").

Gorsek as modified by Rao and Velez, above, describes the treatment of ocular inflammation or macular degeneration using an antioxidant composition, but does not include omega-3 fatty acids such as DHA or omega 3-fatty acids in the composition.

Troyer describes a composition containing blackcurrant seed oil, a source of both omega-3 and omega-6 fatty acids, as well as cod liver oil, a source of the omega-3 fatty acid DHA, for the promotion of ocular health and treatment of dry-eye syndrome.

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the omega-3 and omega-6 fatty acid composition of Troyer with the composition of Gorsek as modified by Rao and Velez to arrive at the

composition of the instant claims. One of ordinary skill in the art would have been motivated to do so because both compositions are directed to the treatment of ocular diseases and the promotion of ocular health, and it is prima facie obvious to combine two elements known by the art as useful for the same purpose to achieve a third element for achieving the exact same purpose. MPEP § 2144.06.

3. Claims 1-4, 8-20, and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek as modified by Rao and Velez as applied to Claims 1-4, 8-14, 16-20, and 24-33 above, and further in view of U.S. Patent 6,365,622 (hereinafter "Cavazza").

Gorsek as modified by Rao and Velez, above, describes the treatment of ocular inflammation or macular degeneration using an antioxidant composition, but does not include L-carnitine in the composition.

Cavazza teaches that L-carnitine is a powerful antioxidant suitable for oral or topical administration in the treatment of diseases brought about by free radicals. (C.1, L.6-8; L.19-28).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the L-carnitine of Cavazza with the composition of Gorsek as modified by Rao and Velez to arrive at the composition of the instant claims. One of ordinary skill in the art would have been motivated to do so because both compositions are directed to the treatment of ocular diseases and the promotion of ocular health, and it is prima facie obvious to combine two elements known by the art as useful for the same purpose to achieve a third element for achieving the exact same purpose. MPEP § 2144.06.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642